CLAIMS

1. A method of testing the purity or stability to degradation of a sample of lamotrigine or a pharmaceutical dosage form comprising lamotrigine, which method comprises assaying the said sample for the presence of a compound selected from 3-amino-6-(2,3-dichlorophenyl)-1,2,4-triazine-5-(4H)-one and N-[5-amino-6-(2,3-dichlorophenyl)-1,2,4-triazine-3-yl]-2,3-dichlorobenzamide.

2. A method according to claim 1 for testing the purity of a sample of lamotrigine, which includes the steps of:

(i) dissolving a sample of lamotrigine in a solvent to produce a sample solution;

(ii) dissolving a sample of 3-amino-6-(2,3-dichlorophenyl)-1,2,4-triazine-5-(4H)-one or N-(5-amino-6-(2,3-dichlorophenyl)-1,2,4-triazine-3-yl]-2,3-dichlorobenzamide in a solvent to product a reference marker standard solution;

(iii) subjecting the sample solution and the standard solution to thin layer chromatography to obtain a TLC chromatogram for each; and

(iv) estimating the intensity of any secondary spot obtained in the chromatogram of the sample solution, which corresponds in Rf value to the reference marker, against the spot due to the reference marker in the chromatogram of the standard solution.

3. A method according to claim 1 for testing the stability to degradation of a pharmaceutical dosage form comprising lamotrigine, which includes the steps of:

(i) dissolving a sample of the dosage form in a solvent to produce a sample solution;

(ii) dissolving a sample of 3-amino-6-(2,3-dichlorophenyl)-1,2,4-triazine-5-(4H)-one in a solvent to produce a reference marker standard solution;

(iii) subjecting the sample solution and the standard solution to thin layer chromatography to obtain a TLC chromatogram for each; and

(iv) estimating the intensity of any secondary spot obtained in the chromatogram of the sample solution, which corresponds in value to the reference marker, against the spot due to the reference marker in the chromatogram of the standard solution.

4. A method according to claim 1 for t sting the stability to degradation of a pharmaceutical dosage form comprising lamotrigine, which includes the steps of:

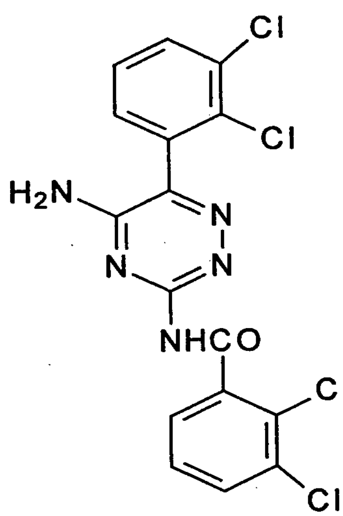
(i) dissolving a sample of the dosage form in a solvent to produce one or more sample solutions;

(ii) dissolving a sample of lamotrigine reference standard in a solvent to produce a standard solution;

(iii) injecting the sample and standard solutions on to an HPLC column, and

(iv) determining the main peak areas of each solution and calculating from these the content of the reference marker 3-amino-6-(2,3-dichlorophenyl)-1,2,4-triazine-5-(4H)-one in the or each sample solution.

5. A compound which is N-[5-amino-6-(2,3-dichlorophenyl)-1,2,4-triazine-3-yl]-2,3-dichlorobenzamide of formula (B):



(B)

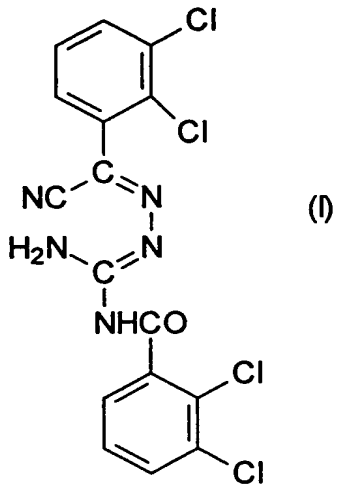
6. A sample of a compound as claimed in claim 5 which is in substantially pure form.

7. A sample according to claim 6 which has a purity level of 90% or above.

8. A process for producing a compound as defined in claim 5, which process comprises:

(i) reacting 2 equivalents of 2,3-dichlorobenzoyl chloride with 1 equivalent of lamotrigine dissolved in pyridine at a temperature of less than 35°C; or

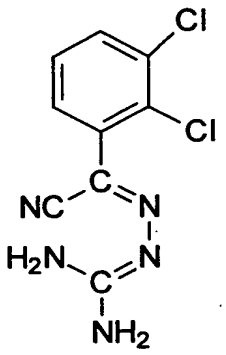
(ii) cyclising a compound of formula (I):



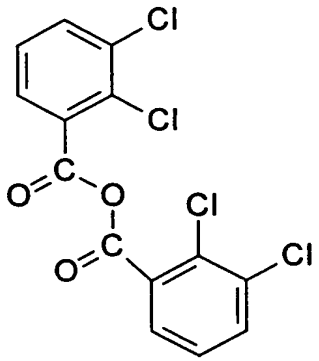
(I)

in propan-1-ol under reflux.

9. A process according to claim 8 wherein, in step (ii), the compound of formula (I) is produced by reacting together compounds of formulae (II) and (III):



(II)



(III)

in the presence of a mineral acid.

10. A process according to claim 9 wherein the compound of formula (II) is produced by treatment of 2,3-dichlorobenzoyl cyanide with a solution of aminoguanidine bicarbonate in sulphuric acid.

11. Use of a compound selected from 3-amino-6-(2,3-dichlorophenyl)-1,2,4-triazine-5-(4H)-one and N-[5-amino-6-(2,3-dichlorophenyl)-1,2,4-triazine-3-yl]-2,3-dichlorobenzamide as a reference marker in testing the purity or stability to degradation of a sample of lamotrigine or a pharmaceutical dosage form comprising lamotrigine.